

# Acurx Announces Scientific Oral and Poster Presented at IDWeek 2022

- Presents research on ibezapolstat's selective activity on healthy bacteria within the gut microbiome in the treatment of *C. difficile* Infection (CDI)
- Emerging ibezapolstat microbiome data demonstrate that favorable effects seen in the Ph1 healthy volunteer study are also observed in the Ph2a trial in CDI patients treated with ibezapolstat
- Currently enrolling Ph2b trial in up to 30 U.S. sites will compare efficacy of ibezapolstat to vancomycin
- Ibezapolstat is FDA QIDP and Fast Track Designated for priority review

STATEN ISLAND, N.Y., Oct. 26, 2022 /PRNewswire/ -- Acurx Pharmaceuticals, Inc. (NASDAQ: ACXP) ("Acurx" or the "Company"), a clinical stage biopharmaceutical company developing a new class of antibiotics for difficult-to-treat bacterial infections, today announced that one scientific oral presentation and one scientific poster highlighting new information about its lead antibiotic ibezapolstat relating to its selectivity against Gram-positive gut microbiota was presented on October 20, 2022 at the Infectious Disease Society of America (IDSA) IDWeek™ 2022 Conference held October 19-23, 2022 in Washington, DC.

Assessed by qPCR and metagenomic sequencing analysis, colonic microbiome Firmicute bacterial populations consistently demonstrated preservation or increased abundance of Lachnospiraceae and Clostridiales throughout the course of ibezapolstat treatment. Furthermore, these emerging data show that the potentially beneficial bacterial species from *C. coccoides* and *C. leptum* groups are preserved in both healthy subjects and CDI patients during ibezapolstat treatment dosing. This persistence or regrowth of healthy microbiota species is associated with beneficial physiologic effects such as preservation of secondary bile acids which are known to protect against CDI recurrence.

According to Kevin Garey, PharmD, MS, FIDSA Professor and Chair, University of Houston College of Pharmacy, "The unexpected finding from further analysis of the Ph2a study is that the beneficial Firmicutes were shown to regrow while patients were receiving ibezapolstat therapy. We have done several follow-up experiments and demonstrated that many of these beneficial Firmicutes have heterogeneous susceptibility to ibezapolstat allowing them to continue to perform their beneficial biologic functions even while a patient is receiving ibezapolstat for their *C. difficile* infection." He further stated: "The totality of the data, including the pioneering vancomycin-controlled healthy volunteer study, suggests that ibezapolstat's effects on the gut microbiome could be predictive of an anti-recurrence effect in CDI patients".

The poster and presentation are available on the Acurx Pharmaceuticals [website](#).

## About Ibezapolstat

Ibezapolstat is a novel, orally administered antibiotic being developed as a Gram-Positive Selective Spectrum (GPSS™) antibacterial. It is the first of a new class of DNA polymerase IIIc inhibitors under development by Acurx to treat bacterial infections. Ibezapolstat's unique spectrum of activity, which includes *C. difficile* but spares other Firmicutes and the important Actinobacteria phyla, appears to contribute to the maintenance of a healthy gut microbiome.

The Company currently is enrolling patients in a Ph2b clinical trial of ibezapolstat to treat patients with *C. difficile* infection (CDI). The Company successfully completed Phase 1 and Phase 2a clinical trials of ibezapolstat. The Phase 2a trial demonstrated 100% clinical cure and 100% sustained clinical cure in patients with CDI, along with beneficial microbiome changes during treatment including overgrowth of Actinobacteria and Firmicutes phylum species while on therapy and new findings which demonstrate potentially beneficial effects on bile acid metabolism. The Ph2b clinical trial is designed to enroll 64 patients and is a randomized (1:1), non-inferiority, double-blind trial of oral ibezapolstat compared to oral vancomycin, a standard of care to treat CDI.

In June 2018, ibezapolstat was designated by the U.S. Food and Drug Administration (FDA) as a Qualified Infectious Disease Product (QIDP) for the treatment of patients with CDI and will be eligible to benefit from the incentives for the development of new antibiotics established under the Generating New Antibiotic Incentives Now (GAIN) Act. In January 2019, FDA granted "Fast Track" designation to ibezapolstat for the treatment of patients with CDI. The CDC has designated *C. difficile* as an urgent threat highlighting the need for new antibiotics to treat CDI.

## About the IDSA and IDWeek

The Infectious Diseases Society of America (IDSA) is a community of over 12,000 physicians, scientists and public health experts who specialize in infectious diseases. Our mission is to improve the health of individuals, communities, and society by promoting excellence in patient care, education, research, public health, and prevention relating to infectious diseases. IDWeek is the joint annual meeting of the Infectious Diseases Society of America (IDSA), Society for Healthcare Epidemiology of America (SHEA), the HIV Medicine Association (HIVMA), the Pediatric Infectious Diseases Society (PIDS), and the Society of Infectious Diseases Pharmacists (SIDP).

**About *Clostridioides difficile* Infection (CDI).** According to the 2017 Update (published February 2018) of the Clinical Practice Guidelines for *C. difficile* Infection by the Infectious Diseases Society of America (IDSA) and Society of Healthcare Epidemiology of America (SHEA), CDI remains a significant medical problem in hospitals, in long-term care facilities and in the community. *C. difficile* is one of the most common causes of health care-associated infections in U.S. hospitals (Lessa, et al, 2015, New England Journal of Medicine). Recent estimates suggest *C. difficile* approaches 500,000 infections annually in the U.S. and is associated with approximately 20,000 deaths annually. (Guh, 2020, New England Journal of Medicine). Based on internal estimates, the recurrence rate of two of the three antibiotics currently used to treat CDI is between 20% and 40% among approximately 150,000 patients treated. We believe the annual incidence of CDI in the U.S. approaches 600,000 infections and a mortality rate of approximately 9.3%.

## About the Microbiome in *Clostridioides difficile* Infection (CDI) and Bile

## Acid Metabolism

*C. difficile* can be a normal component of the healthy gut microbiome, but when the microbiome is thrown out of balance, the *C. difficile* can thrive and cause an infection. After colonization with *C. difficile*, the organism produces and releases the main virulence factors, the two large clostridial toxins A (TcdA) and B (TcdB). (Kachrimanidou, *Microorganisms* 2020, 8, 200; doi:10.3390/microorganisms8020200.) TcdA and TcdB are exotoxins that bind to human intestinal epithelial cells and are responsible for inflammation, fluid and mucous secretion, as well as damage to the intestinal mucosa.

Bile acids perform many functional roles in the GI tract, with one of the most important being maintenance of a healthy microbiome by inhibiting *C. difficile* growth. Primary bile acids, which are secreted by the liver into the intestines, promote germination of *C. difficile* spores and thereby increase the risk of recurrent CDI after successful treatment of an initial episode. On the other hand, secondary bile acids, which are produced by normal gut microbiota through metabolism of primary bile acids, do not induce *C. difficile* sporulation and therefore protect against recurrent disease. Since ibezapolstat treatment leads to minimal disruption of the gut microbiome, bacterial production of secondary bile acids continues which may contribute to an anti-recurrence effect.

## About the Ibezapolstat Phase 2 Clinical Trial

The multicenter, open-label single-arm segment of this study (Phase 2a) is to be followed by a double-blind, randomized, active-controlled segment (Phase 2b) which, together, comprise the Phase 2 clinical trial. The Phase 2 clinical trial is designed to evaluate ibezapolstat in the treatment of CDI. Phase 2a of this trial is completed and was an open-label cohort of up to 20 subjects from study centers in the United States. In this cohort, 10 patients with diarrhea caused by *C. difficile* were treated with ibezapolstat 450 mg orally, twice daily for 10 days. All patients were followed for recurrence for  $28 \pm 2$  days. Per protocol, after 10 patients of the projected 20 Phase 2a patients completed treatment, the Trial Oversight Committee assessed the safety and tolerability and made its recommendation regarding early termination of the Phase 2a study. Based on the recommendation of Acurx's Scientific Advisory Board (SAB) and Trial Oversight Committee, we terminated enrollment in Phase 2a early and are now advancing to Phase 2b. The SAB unanimously supported the early termination of the Phase 2a trial after 10 patients were enrolled in the trial instead of 20 patients as originally planned. The early termination was based on the evidence of meeting the primary and secondary endpoints of eliminating the infection (100%), with no recurrences of infection (100%), and with an acceptable adverse event profile. In the upcoming Phase 2b, approximately 64 additional patients with CDI will be enrolled and randomized in a 1:1 ratio to either ibezapolstat 450 mg every 12 hours or vancomycin 125mg orally every 6 hours, in each case, for 10 days and followed for  $28 \pm 2$  days following the end of treatment for recurrence of CDI. The two treatments will be identical in appearance, dosing times, and number of capsules administered to maintain the blind. This Phase 2 clinical trial also will evaluate pharmacokinetics (PK) and microbiome changes and continue to test for anti-recurrence microbiome properties, including the change from baseline in alpha diversity and bacterial abundance, especially overgrowth of healthy gut microbiota Actinobacteria and Firmicute phylum species during and after therapy.

## About Acurx Pharmaceuticals, Inc.

Acurx Pharmaceuticals is a clinical stage biopharmaceutical company focused on developing new antibiotics for difficult to treat infections. The Company's approach is to develop antibiotic candidates that target the DNA polymerase III $\epsilon$  enzyme and its R&D pipeline includes antibiotic product candidates that target Gram-positive bacteria, including *Clostridioides difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin resistant *Enterococcus* (VRE) and drug-resistant *Streptococcus pneumoniae* (DRSP).

To learn more about Acurx Pharmaceuticals and its product pipeline, please visit [www.acurxpharma.com](http://www.acurxpharma.com).

## Forward-Looking Statements

Any statements in this press release about our future expectations, plans and prospects, including statements regarding our strategy, future operations, prospects, plans and objectives, and other statements containing the words "believes," "anticipates," "plans," "expects," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: whether ibezapolstat will benefit from the QIDP designation; whether ibezapolstat will advance through the clinical trial process on a timely basis; whether the results of the clinical trials of ibezapolstat will warrant the submission of applications for marketing approval, and if so, whether ibezapolstat will receive approval from the FDA or equivalent foreign regulatory agencies where approval is sought; whether, if ibezapolstat obtains approval, it will be successfully distributed and marketed; and other risks and uncertainties described in the Company's annual report filed with the Securities and Exchange Commission on Form 10-K for the year ended December 31, 2021, and in the Company's subsequent filings with the Securities and Exchange Commission. Such forward-looking statements speak only as of the date of this press release, and Acurx disclaims any intent or obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements, except as may be required by law.


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